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JUL 21 2000

K001317

510(k) Summary

Submitted by	Del Mar Medical Systems 1621 Alton Parkway Irvine, California
Contact Person	Ed Crespin
Date Prepared	April 26, 2000
Proprietary Name	Aria™
Common Name	Digital Holter Recorder
Classification Name	Medical tape recorder
Predicate Device	Del Mar Avionics Model 483 DigiCorder®
Description of Device	The Aria recorder is a compact, lightweight digital recorder designed for maximum comfort and convenience while accurately recording 24+ hours of three-channel ECG ambulatory data. The memory storage is built-in, with no media handling required. No patient cable is needed (detachable direct leads). The ECG data can be retrieved by any current Del Mar scanner system.
Intended Use of Device	The Aria recorder is intended for collection of continuous ambulatory ECG data in digital format. Subsequent retrieval and analysis of this data is to be conducted under the supervision of a licensed physician.
Technical Considerations	The fundamental technology of the Aria recorder is the same as the predicate device. It takes advantage of the current art in operational amplifier design, memory miniaturization, and current expansive availability of surface mount parts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2000

Delmar Medical
Ed Crespin
Vice President, Engineering
1621 Alton Parkway
Irvine, CA 92606

Re: K001317
Trade Name: ARIA™ Digital Holter Recorder
Regulatory Class: II (two)
Product Code: MWJ
Dated: April 26, 2000
Received: April 26, 2000

Dear Mr. Crespin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Premarket Notification
Del Mar Medical Systems
***Aria™* Digital Holter Recorder**
April 26, 2000

510(k) Number (if known): K001317

Device Name: *Aria*™ Digital Holter Recorder

Indications for Use

The Aria recorder is intended for use as an ECG data recorder. It provides for the continuous collection of three-channels of ambulatory ECG for 24+ hours. The recorder provides no analysis. It allows the user to mark significant times with an event button.

(PLEASE DO NOT WRTIE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001317

Prescription Use_____ OR Over-the-Counter Use_____
(Per 21 CFR §801.109)